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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/340,338 06/25/99 FOTINOS

S 1581/120

002101
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HM22/0406

EXAMINER

WARE, T

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

04/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/340,338	Applicant(s) FOTINOS, SPIROS	
	Examiner Todd D Ware	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 26-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24, 26-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 20) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Receipt of request for extension of time (granted) and amendment both filed 1-25-01 is acknowledged. Claims 1, 2, 8, 9, 12, 17 and 21 have been amended as requested. Claims 25 and 37-38 have been canceled.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-24 and 26-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Amendment with "consisting of a single layer of a filmogenic polymer" in claims 1-24 and 26-36 is new matter. Applicant has stated that support for the amendment can be found on page 7, lines 3-13, however it appears that the specification only teaches that the invention is a disk and that it does not require a backing or a release liner. It does not state that the disk is a single layer. It is submitted that a disk may have multiple layers, yet remain a disk.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 5 recites the broad recitation "a vasodilator", and the claim also recites a smooth muscle relaxant, a parasympathetic stimulator, a renin-angiotensin system inhibitor, an alpha-blocker and a calcium channel blocker which are narrower statements of the range/limitation.

Claims 7 and 22 list "a phentolamine" twice. Correction is requested.

Recitation of "derivative" in claim 8 is indefinite since it is not specified what the derivative is. Derivatives of compounds are considered "so indefinite as to be meaningless" since they "cover such a large number of compounds, whose structures

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are not defined, that the specification does not support the claims" (Petrolite v. Watson, Comr. Pats. 113 USPQ 248, 1957). In the instant application, the specification does mention a cyclohexanol derivative but does not define what derivatives the claim is intended to encompass.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1-8, 13, 18-24, 27, 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Denzer (6,007,836; hereafter '836).

'836 discloses transdermal vasodilator systems for producing and maintaining the erection of a male penis comprising a combination of vasodilators such as prostaglandin E1, papaverine, phentolamine and polymer films (abstract; C7, L38-C8, L5; C8, L53-C9, L6). '836 also discloses the inclusion of isopropyl myristate and polyethylene glycol (C8, L41-52). The compositions of '836 produce an erection "on demand, immediately before sexual intercourse" and are therefore thought to be released in less than one hour. '836 also discloses that when the vasodilator system is used in conjunction with a condom, the outer barrier is unnecessary. Therefore, the system would have only one layer (C15, L22-30).

Response to Arguments

7. Applicant's arguments filed 1-25-01 have been fully considered but they are not persuasive. Applicant has amended the claims to include the limitation where the delivery device is a single layer of filmogenic polymer and argues that the cited art does not disclose a delivery device where consisting of a single layer. '836 discloses that when the vasodilator system is used in conjunction with a condom, the outer barrier is unnecessary. Therefore, the system would have only one layer (C15, L22-30).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-8, 10-11, 13, 17-27, 29, 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denzer (6,007,836; hereafter '836).

'836 teaches transdermal vasodilator systems for producing and maintaining the erection of a male penis comprising a combination of vasodilators such as prostaglandin E1, papaverine, phentolamine and polymer films (abstract; C7, L38-C8, L5; C8, L53-C9, L6). '836 also discloses the inclusion of isopropyl myristate and polyethylene glycol (C8, L41-52). '836 does not teach the amount of polyethylene glycol to include in the composition. However, it is submitted that this is a manipulatable parameter that would be obvious to one skilled in the art at the time of the invention to manipulate in an effort

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to increase or decrease flexibility of the polymer film. The compositions of '836 produce an erection "on demand, immediately before sexual intercourse" and are therefore thought to be released in less than one hour. '836 does not state whether the penile surface requires pre-wetting. It is submitted that since it ^{does} not say that wetting the surface is required, no pre-wetting is necessary. It is also submitted that pre-wetting the surface would be obvious to one skilled in the art at the time of the invention to aid in adhesion of the patch to the skin, since this would aid in creating a vacuum.

10. Claims 1-8, 10-11, 13-14, 17-30, 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denzer (6,007,836; hereafter '836) in view of Belsole (4,696,821; hereafter '821).

'836 is relied upon for all that it teaches as stated previously.

'821 is relied upon for teaching that polyvinylpyrrolidone film is an effective means for controlling the release of an active agent when administered transdermally. '821 also teaches the inclusion of plasticizers in the polyvinylpyrrolidone films wherein the plasticizer is PEG 400. The amount of plasticizer is unclear since '821 teaches weight per volume of liquid. Should applicants traverse on the grounds that the amount of plasticizer of '821 is outside the instant ranges, applicants are requested to submit evidence pertaining thereto. Furthermore, it is submitted that the ranges pertaining to the amount of plasticizer is a manipulatable parameter and it would be obvious to one skilled in the art at the time of the invention to adjust the amount of plasticizer in the composition to increase or decrease the flexibility of the film.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to construct the films of '836 from polyvinylpyrrolidone with the expectation that these films would control the release of drug from the patch and the motivation lying therein.

11. Claims 1-8, 10-11, 13, 15-24, 26-27, 29, 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denzer (6,007,836; hereafter '836) in view of Postaire (FR 2710649; hereafter '649).

'836 is relied upon for all that it teaches as stated previously.

'649 is relied upon for teaching transdermal films formulated as a biodegradable patch comprising gliadin gel based on plant prolamines extracted from cereals (wheat) (abstract, p1).

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to construct the polymer films of '836 from gliadin with the motivation to provide a transdermal patch to treat impotence that is biodegradable and the expectation that gliadin transdermal patches are biodegradable.

Response to Arguments

12. Applicant's arguments filed 1-25-01 have been fully considered but they are not persuasive. Applicant has amended the claims to include the limitation where the delivery device is a single layer of filmogenic polymer and argues that the cited art does not disclose a delivery device where consisting of a single layer. '836 discloses that

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when the vasodilator system is used in conjunction with a condom, the outer barrier is unnecessary. Therefore, the system would have only one layer (C15, L22-30).

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 7:30 AM - 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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April 4, 2001